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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,341	11/28/2000	Avi J. Ashkenazi	P1805R1	7279

9157 7590 09/16/2002

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/724,341	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-88 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Fax Transmission-Restriction Election.

DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, 7, 9, 11-13, 15-22, 25, 27, 29-31, 34-37 drawn to a method of inhibiting or neutralizing TALL-1 polypeptide biological activity and a method of inhibiting or neutralizing APRIL polypeptide biological activity comprising exposing cells to TACI, classified in Class 514, subclass 8.

II. Claims 1, 2, 5, 6, 8, 10, 11-13, 15-20, 23, 24, 26, 28-31, 34-37 drawn to a method of inhibiting or neutralizing TALL-1 polypeptide biological activity and a method of inhibiting or neutralizing APRIL polypeptide biological activity comprising exposing cells to BCMA, classified in Class 514, subclass 8.

III. Claims 1, 2, 14, 17-20, 32, 35-37 drawn to a method of inhibiting or neutralizing TALL-1 polypeptide biological activity and a method of inhibiting or neutralizing APRIL polypeptide biological activity comprising exposing cells to TACI receptor antibody, classified in Class 424, subclass 130.1.

IV. Claims 1, 2, 14, 17-20, 32, 35-37 drawn to a method of inhibiting or neutralizing TALL-1 polypeptide biological activity and a method of inhibiting or neutralizing APRIL polypeptide biological activity comprising exposing cells to BCMA receptor antibody, classified in Class 424, subclass 130.1.

V. Claims 1, 2, 14, 17-20, 32, 35-37 drawn to a method of inhibiting or neutralizing TALL-1 polypeptide biological activity and a method of inhibiting or neutralizing APRIL polypeptide biological activity comprising exposing cells to TALL-1 polypeptide antibody, classified in Class 424, subclass130.1.

VI. Claims 1, 2, 14, 17-20, 32, 33, 35-37 drawn to a method of inhibiting or neutralizing TALL-1 polypeptide biological activity and a method of inhibiting or neutralizing APRIL polypeptide biological activity comprising exposing cells to APRIL polypeptide antibody, classified in Class 424, subclass 130.1.

VII. Claims 38-40, drawn to a method of enhancing or stimulating TCAI polypeptide comprising exposing cells to anti-TACI agonist antibody; classified in Class 424, subclass 130.1.

VIII. Claims 41-43, drawn to a method of enhancing or stimulating BCMA polypeptide comprising exposing cells to anti-BCMA agonist antibody; classified in Class, 424, subclass 130.1.

IX. Claims 44-48 and 53-58, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI, wherein pathological condition is an immune related disease, classified in Class 514, subclass 8.

X. Claims 44, 45, 50-55 and 60-61, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI, wherein pathological condition is cancer, classified in Class 514, subclass 8.

XI. Claims 44, 45, 47, 49, 53-55, 57 and 59, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI, wherein pathological condition is an autoimmune disease, classified in Class 514, subclass 8.

XII. Claims 44, 45 and 53-55, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI, wherein pathological condition is an infectious disease, classified in Class 514, subclass 8.

XIII. Claims 44-48 and 53-58, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA, wherein pathological condition is an immune related disease, classified in Class 514, subclass 8.

XIV. Claims 44, 45, 50-55 and 60-61, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA, wherein pathological condition is cancer, classified in Class 514, subclass 8.

XV. Claims 44, 45, 47, 49, 53-55, 57 and 59, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA, wherein pathological condition is an autoimmune disease, classified in Class 514, subclass 8.

XVI. Claims 44, 45 and 53-55, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA, wherein pathological condition is an infectious disease, classified in Class 514, subclass 8.

XVII. Claims 44-48 and 53-58, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI antibody, wherein pathological condition is an immune related disease, classified in Class 424, subclass 130.1.

XVIII. Claims 44, 45, 50-55 and 60-61, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI antibody, wherein pathological condition is cancer, classified in Class 424, subclass 130.1.

XIX. Claims 44, 45, 47, 49, 53-55, 57 and 59, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI antibody, wherein pathological condition is an autoimmune disease, classified in Class 424, subclass 130.1.

XX. Claims 44, 45 and 53-55, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TACI antibody, wherein pathological condition is an infectious disease, classified in Class 424, subclass 130.1.

XXI. Claims 44-48 and 53-58, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA antibody, wherein pathological condition is an immune related disease, classified in Class 424, subclass 130.1.

XXII. Claims 44, 45, 50-55 and 60-61, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA antibody, wherein pathological condition is cancer, classified in Class 424, subclass 130.1.

XXIII. Claims 44, 45, 47, 49, 53-55, 57 and 59, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA antibody, wherein pathological condition is an autoimmune disease, classified in Class 424, subclass 130.1.

XXIV. Claims 44, 45 and 53-55, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering BCMA antibody, wherein pathological condition is an infectious disease, classified in Class 424, subclass 130.1.

XXV. Claims 44-48 and 53-58, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TALL-1 antibody, wherein pathological condition is an immune related disease, classified in Class 424, subclass 130.1.

XXVI. Claims 44, 45, 50-55 and 60-61, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TALL-1 antibody, wherein pathological condition is cancer, classified in Class 424, subclass 130.1.

XXVII. Claims 44, 45, 47, 49, 53-55, 57 and 59, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TALL-1 antibody, wherein pathological condition is an autoimmune disease, classified in Class 424, subclass 130.1.

XXVIII. Claims 44, 45 and 53-55, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering TALL-1 antibody, wherein pathological condition is an infectious disease, classified in Class 424, subclass 130.1.

XXIX. Claims 44-48 and 53-58, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering APRIL antibody, wherein pathological condition is an immune related disease, classified in Class 424, subclass 130.1.

XXX. Claims 44, 45, 50-55 and 60-61, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering APRIL antibody, wherein pathological condition is cancer, classified in Class 424, subclass 130.1.

XXXI. Claims 44, 45, 47, 49, 53-55, 57 and 59, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition

comprising administering APRIL antibody, wherein pathological condition is an autoimmune disease, classified in Class 424, subclass 130.1.

XXXII. Claims 44, 45 and 53-55, drawn to a method of treating a Tall-1 related pathological condition and a method of treating APRIL related pathological condition comprising administering APRIL antibody, wherein pathological condition is an infectious disease, classified in Class 424, subclass 130.1.

XXXIII. Claims 63-64, drawn to a composition comprising a TALL-1 polypeptide antagonist and a carrier, classified in Class 514, subclass 8.

XXXIV. Claims 65-66, drawn to a composition comprising an APRIL polypeptide antagonist and a carrier, classified in Class 514, subclass 8.

XXXV. Claims 67-88, drawn to an antibody that binds APRIL polypeptide and hybridoma, classified in Class 435, subclass 536 and Class 530, subclass 387.1.

4. Groups I-XXXII are different methods. A method of inhibiting or neutralizing and a method of enhancing or stimulating and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. The products of Groups XXXIII/XXXIV/XXXV are differ from each other in that they are structurally and functionally distinct products. The product of Groups XXXIV/XXXV, although they are both proteins are structurally unique proteins (i.e. antibody and polypeptide). Antibodies and polypeptides function at a different level and are made through different tissue type.

6. Groups I- XXXII and XXXIII-XXXV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group XXXV can be used for affinity purification, in addition to the methods recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. This application contains claims directed to the following patentably distinct species of the claimed Inventions I and II, wherein TACI/BCMA receptor link is:

A) polyethylene glycol,
B) polypropylene glycol, or
C) polyoxyalkylene.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions IX, XIII, XVII, XXI, XXV and XXIX: wherein immune related disease is:

A) Sjogren's syndrome,
B) Hashimoto's thyroiditis,
C) juvenile chronic arthritis, or
D) others, recited in specification page 45.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. This application contains claims directed to the following patentably distinct species of the claimed Inventions X, XIV, XVIII, XXII, XXVI and XXX: wherein cancer is:

A) adenocarcinoma,
B) lymphoma,
C) blastoma,
D) melanoma,
E) sarcoma, or
F) others, recited in the specification page 44.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. This application contains claims directed to the following patentably distinct species of the claimed Inventions XI, XV, XIX, XXIII, XXVII and XXXI: wherein Autoimmune disease is:

A) throiditis,
B) rheumatoid arthritis,
C) psoriasis,
D) multiple sclerosis, or
E) others, recited in specification page 46.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. This application contains claims directed to the following patentably distinct species of the claimed Inventions XII, XVI, XX, XIV, XXVIII and XXXII: wherein infectious disease is:

A) AIDS,
B) Hepatitis A,
C) Hepatitis B,
D) Hepatitis C, or
E) others, recited in specification page 45.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the

election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
January 15, 2002

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/15/02